



UNIVERSITY OF  
PENNSYLVANIA  
HEALTH SYSTEM

**PENN Orthopaedic Institute**

Department of Orthopaedic Surgery

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Reconstructive Surgery of  
the Shoulder and Elbow*

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Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: DOCKET NO. 97N-484S

To Whom It May Concern:

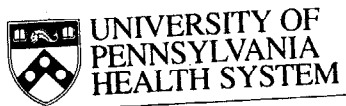
It has recently come to my attention via an allograft procurement company that the above-mentioned docket could result in allograft material being regulated as a medical device. I do not know what the intention of this proposal is; however, it has wide reaching ramifications, some of which I think would be disastrous to patients in the United States. We use allograft bone on numerous occasions to help us replace bone in patients who are missing it. Situations in which this may be used include revision joint replacements, post-traumatic fracture work, spinal fusions and fusions involving other joints. My understanding is that the FDA already regulates the safety of these tissues. I can't think of why the FDA would want to regulate their use as a medical device and require such things as sponsoring clinical trials. The added expense of this, I am certain, would impede companies and bone banks from providing an adequate supply of this material. The FDA should look long and hard at this proposal and assess all of its ramifications.

Sincerely,

Gerald R. Williams, Jr., M.D.  
Associate Professor of Orthopaedic Surgery

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